No. 04-623

In the Supreme Court of the United States

ALBERTO R. GONZALES, Attorney General, et al,

Petitioners,

v.

STATE OF OREGON, et al,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR RESPONDENT STATE OF OREGON

HARDY MYERS
Attorney General of Oregon
PETER SHEPHERD
Deputy Attorney General
*MARY H. WILLIAMS
Solicitor General
ROBERT M. ATKINSON
Assistant Attorney General
400 Justice Building
Salem, Oregon 97301-4096
Phone: (503) 378-4402
Counsel for Respondent
State of Oregon

*Counsel of Record

QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of a state law purporting to authorize such distribution.

TABLE OF CONTENTS

Page

Question Presented..... i

Statement..... 1

Summary of Argument 10

Argument 12

I. The U.S. Attorney General's threatened action would nullify the DWDA..... 17

A. The DWDA does not merely "decriminalize physician assisted suicide." 18

B. The principles underlying the presumption against preemption apply here..... 20

II. The CSA does not itself prohibit the uses of controlled substances permitted by the DWDA, and it does not authorize the U.S. Attorney General to do so. 21

A. Neither the text of the CSA nor judicial interpretations of that text suggest that Congress intended to displace the States' traditional power to regulate medical practice, even when controlled substances are involved..... 21

1. The text generally and judicial interpretations..... 21

2. The "anti-preemption clause" 26

B. The CSA contains no clear statement of intent to displace state regulation of medicine. 27

1. Because the U.S. Attorney General's action here would displace traditional state authority, a clear statement is a condition precedent to that action or to *Chevron* deference. 30

2. The clear statement rule applies more broadly than petitioners acknowledge..... 31

3. The CSA reflects Congress's intent to respect the States' traditional role in regulating medical practice..... 34

C. A clear statement is required here to support the U.S. Attorney General's threat to displace the States' traditional regulation of medical practice. 38

D. A clear statement is required here to support the U.S. Attorney General's threat because it would push the boundaries of Congress's authority under the Commerce Clause. 42

III. The Court should reject this unprecedented attempt by an agency official to resolve a disputed issue of social and medical policy that is reserved to the States and should reemphasize the vital role State sovereignty plays in our federal system and the need for Congress to speak clearly when it intends to interfere with that role. 48

Conclusion 50

TABLE OF AUTHORITIES

Page

Cases Cited

Argentine Republic v. Amerada Hess Shipping, 488 U.S. 428 (1989)..... 27

California Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc., 519 U.S. 316 (1997)..... 33

California Fed. Sav. & Loan Ass'n v. Guerra, 479 U.S. 272 (1987)..... 20

Chevron U.S.A. v. Natural Res. Def. Council, 467 U.S. 837 (1984)..... 11, 30, 31

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992)..... 21

Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261 (1990)..... 40

Department of Revenue of Ore. v. *ACF Industries, Inc.*, 510 U.S. 332 (1994)..... 20, 38

Doe v. Bolton, 410 U.S. 179 (1973)..... 23

Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council, 485 U.S. 568 (1988)..... 30

ETSI Pipeline Project v. Missouri, 484 U.S. 495 (1988)..... 31

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000)..... 31

Gade v. National Solid Wastes Management Ass'n., 505 U.S. 88 (1992)..... 29

Garcia v. San Antonio Metro. Transit Auth.,
469 U.S. 528 (1985) 28, 46

Geier v. American Honda Motor Co.,
529 U.S. 861 (2000) 35

Gonzales v. Raich,
545 U.S. ___,
125 S. Ct. 2195 (2005) 3, 4, 14, 15, 22, 41, 43-46

Gregory v. Ashcroft,
501 U.S. 452 (1991) 28, 30, 31, 32, 33, 34

Grinspoon v. Drug Enforcement Admin.,
828 F.2d 881 (1st Cir. 1987) 25

Hammer v. Dagenhart,
247 U.S. 251 (1918) 47

Hillsborough County v. Automated Medical Labs.,
471 U.S. 707 (1985) 30, 35, 38

Hisquierdo v. Hisquierdo,
439 U.S. 572 (1979) 33

Humphreys v. Drug Enforcement Admin.,
96 F.3d 658 (3rd Cir. 1996) 22

INS v. St. Cyr,
533 U.S. 289 (2001) 45

Jones v. United States,
529 U.S. 848 (2000) 20, 30, 33, 43, 46, 47

Linder v. United States,
268 U.S. 5 (1925) 23, 47

McCulloch v. Maryland,
4 Wheat. 316 (1819) 47

Medtronic Inc. v. Lohr,
518 U.S. 470 (1996) 26, 38, 39, 41, 42, 48, 49

Mississippi Band of Choctaw Indians v. Holyfield,
490 U.S. 30 (1989) 16, 17, 35

National Cable & Telecommunications Assn. v. Brand X Internet Services,
545 U.S. ___ (June 27, 2005) 31

New State Ice Co. v. Liebmann,
285 U.S. 262 (1932) 40

New York v. United States,
505 U.S. 144 (1992) 47

NLRB v. Action Automotive, Inc.,
469 U.S. 490 (1985) 27, 43

Perez v. United States,
402 U.S. 146 (1971) 43

Printz v. United States,
521 U.S. 898 (1997) 47

Raygor v. Regents of the University of Minnesota,
534 U.S. 533 (2002) 32

Retail Clerks v. Schermerhorn,
375 U.S. 96 (1963) 26

Rice v. Santa Fe Elevator Corp.,
331 U.S. 218 (1947) 28, 32, 33, 35

Robinson v. California,
370 U.S. 660 (1962) 47

Rush Prudential HMO, Inc. v. Moran,
536 U.S. 355 (2002) 33

Solid Waste Agency of Northern Cook Cty. v. Army Corps of Engineers,
531 U.S. 159 (2001) 17, 28, 30, 42, 43, 46

Touby v. United States,
500 U.S. 160 (1991) 4, 24

United States v. Bass,
404 U.S. 336 (1971) 20, 29, 32

United States v. Collier,
478 F.2d 268 (5th Cir. 1973) 23

United States v. Darby,
312 U.S. 100 (1941) 47

United States v. Five Gambling Devices,
346 U.S. 441 (1953) 46

United States v. Kahriger,
345 U.S. 22 (1953) 47

United States v. Lopez,
514 U.S. 549 (1995) 29, 30, 32, 43, 46, 47

United States v. Moore,
423 U.S. 122 (1975) 9, 22, 36

United States v. Morrison,
529 U.S. 598 (2000) 32, 46, 47

United States v. Rosen,
582 F.2d 1032 (5th Cir. 1978) 22

United States v. Rosenberg,
515 F.2d 190 (9th Cir.),
cert. denied, 423 U.S. 1031 (1975) 23

Vacco v. Quill,
521 U.S. 793 (1997) 40, 44

Washington v. Glucksberg,
521 U.S. 702 (1997) 6, 8, 9, 12, 13, 40

Whalen v. Roe,
429 U.S. 589 (1977) 38

Wickard v. Filburn,
317 U.S. 111 (1942) 44

Will v. Michigan Dept. of State Police,
491 U.S. 58 (1989) 29, 40

Constitutional and Statutory Provisions

5 U.S.C. §§ 551-559 5

7 U.S.C. § 2156(h) 26

15 U.S.C. § 78bb(a) 27

21 U.S.C. § 801 3

21 U.S.C. § 802(21) 4

21 U.S.C. § 811 4

21 U.S.C. § 811(a) 4, 24

21 U.S.C. § 811(a)(1)(A) 24

21 U.S.C. § 811(a)(1)(B) 24

21 U.S.C. § 811(b) 5, 24

21 U.S.C. § 811(c) 5

21 U.S.C. § 811(f) 6, 15

21 U.S.C. § 812 4

21 U.S.C. § 812(b)(1) 4

21 U.S.C. § 812(b)(2)(B) 25

21 U.S.C. § 821(f) (1970) 36

21 U.S.C. § 822(b) 4

21 U.S.C. § 823(a) 6

21 U.S.C. § 823(b) 6

21 U.S.C. § 823(d) 6

21 U.S.C. § 823(e) 6
21 U.S.C. § 823(f) 6, 36
21 U.S.C. § 824(a) 6
21 U.S.C. § 824(a)(4) 19
21 U.S.C. § 824(a)(4) (1984) 36
21 U.S.C. § 841(a)(1) 3, 21
21 U.S.C. § 844(a) 22
21 U.S.C. § 903 ..... 26, 35
30 U.S.C. § 955(a) 27
Or. Rev. Stat. §§ 127.800 through 127.995 1
Or. Rev. Stat. § 127.800(12) 2
Or. Rev. Stat. § 127.805 1
Or. Rev. Stat. § 127.810 1
Or. Rev. Stat. § 127.815 ..... 1, 2
Or. Rev. Stat. § 127.815(1)(j) 3
Or. Rev. Stat. § 127.815(c) 2
Or. Rev. Stat. § 127.820 ..... 1, 2
Or. Rev. Stat. § 127.825 2
Or. Rev. Stat. § 127.840 1
Or. Rev. Stat. § 127.855 3
Or. Rev. Stat. § 127.865 3
Or. Rev. Stat. § 163.125(1)(b) 18

Administrative Rules

21 C.F.R. § 1306.04 7
21 C.F.R. § 1306.04(a) (1971) 35

Other Authorities

Cass R. Sunstein,
Chevron Step Zero, 92 Va. L. Rev.
(forthcoming April 2006) 31

Oregon Department of Human Services,
Fifth Annual Report on Oregon's Death With Dignity Act (2003) 43

Oregon Department of Human Services,
Seventh Annual Report on Oregon's Death with Dignity Act (2005) 13, 19, 43, 45

Thomas W. Merrill & Kristin E. Hickman,
Chevron's Domain, 89 Geo. L. J. 833 (2001) 31

STATEMENT

Exercising its traditional power to regulate the practice of medicine, Oregon became the first state to authorize physicians to prescribe controlled substances to competent terminally ill adults to allow them to control the time, place, and manner of death. The question presented in this case is whether physicians acting in accordance with Oregon's law violate the Controlled Substances Act (CSA) or, in the alternative, whether the CSA authorizes the U.S. Attorney General to determine that they do.

1. a. In 1994, the people of Oregon enacted by initiative the Oregon Death with Dignity Act (DWDA).[1] The DWDA establishes tightly controlled procedures allowing physicians to prescribe Schedule II controlled substances to competent terminally ill adult patients in sufficient kind and quantity to permit the patient to control the time, place, and manner of death. Or. Rev. Stat. §§ 127.800 through 127.995. Or. Rev. Stat. § 127.805; App. to Pet. for Cert. 163a.

To comply with the DWDA, a patient must make an oral request to his or her attending physician and, after a 15-day waiting period, make a written request witnessed by at least two individuals. Or. Rev. Stat. § 127.810; § 127.840. Two doctors must determine that the patient is mentally capable, is "suffering from a terminal disease," and has voluntarily expressed a wish to accelerate the dying process. Or. Rev. Stat. § 127.805; § 127.815; § 127.820. A patient is "terminally ill" if the person has "an incurable and irreversible disease that has been medically confirmed and

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[1] In 1997, the Oregon legislature referred to the people a measure that would have repealed the DWDA. The repeal measure was rejected in the November 1997 election by 60% of the voters.

will, within reasonable medical judgment, produce death within six months." Or. Rev. Stat. § 127.800(12).

In addition to determining the patient's Oregon residence, the attending physician must also ensure that the patient has made an informed decision, which requires that the patient be advised of the medical diagnosis, the prognosis, the potential risks associated with the medications to be prescribed, the probable result of taking the medication, and the feasible alternatives, including comfort care, hospice care, and pain management. Or. Rev. Stat. § 127.815. The attending physician must refer the patient to a consulting physician "for medical confirmation of the diagnosis" and to verify that the patient is capable and acting voluntarily. Or. Rev. Stat. § 127.815(c); § 127.820. The consulting physician must "examine the patient and his or her relevant medical records and confirm, in writing" the diagnosis. Or. Rev. Stat. § 127.820. The attending and consulting physicians must refer the patient for counseling if either believes that the patient "may be suffering from a psychiatric or psychological disorder or depression causing impaired judgment." Or. Rev. Stat. § 127.825. Once a request from a qualifying patient has been properly documented and witnessed, and all waiting periods have expired, the attending physician may prescribe, but not administer, medication to enable the patient to end his or her life in a humane and dignified manner.[2]

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[2] The DWDA has been described as authorizing "physician assisted suicide." That description is potentially misleading inasmuch as neither the physicians who prescribe nor the pharmacists who dispense drugs under the DWDA may provide physical assistance to the patient. The term may be overbroad in another sense. To the extent that the dictionary describes "suicide" as taking one's own life, it might technically be accurate as applied to the DWDA. But the DWDA is available to only a very small subset of those who might choose to end their lives. Most significantly, as described above, it is available only to those whose death is predictably imminent. Moreover, it imposes stringent restrictions, foremost among them those dealing with mental competence and the concurrence of two physicians, on people who would take advantage of its provisions.

The DWDA immunizes physicians and pharmacists who act in compliance with its comprehensive procedures from state civil or criminal sanctions, and from any professional disciplinary action based on that conduct. The DWDA also requires the attending physician and other participating health-care providers to comply with medical documentation and reporting requirements. Or. Rev. Stat. § 127.815(1)(j); § 127.855; § 127.865.

b. In 1970, Congress enacted the CSA, 21 U.S.C. § 801 *et seq.*, Title II of the Comprehensive Drug Abuse Prevention and Control Act, to address the "perceived need to consolidate the growing number of piecemeal drug laws and to enhance federal drug enforcement powers[.]" *Gonzales v. Raich*, 545 U.S. ___, ___, 125 S. Ct. 2195, 2203 (2005). Because Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels, "[t]he main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." 125 S. Ct. at 2203 (footnote omitted).

With the CSA, Congress created a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. § 841(a)(1); *Raich*, 125 S. Ct. at 2203-04. The CSA categorizes all controlled substances into five schedules, based on their accepted medical uses, the potential for abuse, and their psychological

and physical effects on the body. 21 U.S.C. §§ 811, 812. Although Congress initially placed various substances on each of the five schedules, it also gave the U.S. Attorney General authority to add substances to or remove them from the schedules and to move them from one schedule to another if he follows the requisite procedures and makes the required findings. Schedule I substances, such as marijuana, have been determined to have no accepted medical use. 21 U.S.C. § 812(b)(1); *Raich*, 125 S. Ct. at 2204. All substances on Schedules II through V, including those prescribed by physicians under the DWDA, have accepted medical uses. Physicians, pharmacists, and other practitioners who dispense controlled substances must obtain a registration from the U.S. Attorney General.[3] Physicians may prescribe controlled substances only "in the course of professional practice or research," 21 U.S.C. § 802(21), and only "to the extent authorized by their registration and in conformity with the other provisions of [the CSA]," 21 U.S.C. § 822(b).

To exercise his authority to schedule or reschedule substances, the U.S. Attorney General must follow a statutorily specified process. 21 U.S.C. § 811(a); *see Touby v. United States*, 500 U.S. 160, 162-63 (1991). He must first request a scientific and medical evaluation from the Secretary of Health and Human Services (Secretary), together with a

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[3] The CSA applies to "practitioners," which, in general terms, it defines to include physicians, dentists, veterinarians, scientific investigators, pharmacists, and others who are licensed by the United States or the jurisdiction in which they practice to distribute, dispense, or conduct research on or analysis of controlled substances. 21 U.S.C. § 802(21); App. to Pet. for Cert. 149a. For convenience, and because Oregon's law applies only to physicians and pharmacists, this brief generally refers only to physicians.

recommendation about whether the substance should be controlled. A substance cannot be scheduled if the Secretary recommends against it. 21 U.S.C. § 811(b). The CSA provides that "[t]he recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters[.]" *Id.* Second, the U.S. Attorney General must consider eight factors, including the substance's potential for abuse, scientific evidence of its pharmacological effect, and the likelihood of dependence. 21 U.S.C. § 811(c). Third, the U.S. Attorney General must comply with the notice-and-hearing provisions of the Administrative Procedure Act (APA), 5 U.S.C. §§ 551-559, which permit comment by interested parties. 21 U.S.C. § 811(a).

In 1974, Congress made changes to the CSA to address treatment of addicts. In enacting the amendments, Congress expressed the intent to "preserve[] the distinctions found in the Controlled Substances Act between the functions of the Attorney General and the Secretary[.]" H.R. Rep. No. 93-884 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029, 3034. Congress specified that all decisions "of a medical nature" were for the Secretary, and law enforcement decisions, such as those relating to security and record keeping, were to be made by the U.S. Attorney General. *Id.*

In 1984, Congress again amended the CSA in the Dangerous Drug Diversion Control Act of 1984 (DCA). Pub. L. No. 98-473, 98 Stat. 2070 (1984). Among other changes, the amendments changed the manner for registering physicians and other practitioners. Under the original 1970 provisions, the U.S. Attorney General was required to register physicians if they were authorized to dispense or conduct research with controlled substances in the state in which they practiced. The DCA amended that provision, adding a "public interest" consideration, which was similar to the existing

registration provisions for manufacturers and distributors. *See* 21 U.S.C. §§ 823(a), (b), (d), (e). The DCA specified five factors to be considered in determining the "public interest," including compliance with state law and threats to public health and safety. 21 U.S.C. § 823(f); H.R. Rep. 98-835, Part I, at 14 (1984). Additionally, the DCA amended the revocation and suspension provisions of the CSA, 21 U.S.C. § 824(a), to conform to changes made to the registration provision. H.R. Rep. 98-835, Part I, at 14.

2. When some members of Congress complained to then-Attorney General Janet Reno that the DWDA authorized a use of controlled substances that violated the CSA, she disagreed. After a "thorough and careful review" by the Justice Department, Attorney General Reno concluded that the CSA was intended "to prevent both the trafficking in [controlled] substances for unauthorized purposes and drug abuse. The particular drug abuse that Congress sought to prevent was that deriving from the drug's 'stimulant, depressive, or hallucinogenic effect on the central nervous system.' 21 U.S.C. § 811(f)." Or. Br. in Opp. Supp. App. 3-4. Attorney General Reno could find no evidence that, "in the CSA, Congress intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice." *Id.* at 4. She noted that the CSA was "essentially silent" about "regulating the practice of medicine that involves legally available drugs," with one exception dealing with treating addicts. "Even more fundamentally, there is no evidence that Congress, in the CSA, intended to assign the [Drug Enforcement Administration] the novel role of resolving the 'earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide,' *Washington v. Glucksberg*, [521 U.S. 702, 735] (1997),

simply because that procedure involves the use of controlled substances." *Ibid.* Determining whether conduct permitted by the DWDA "falls outside the legitimate practice of medicine and is inconsistent with the public interest" are "fundamental questions of morality and public policy" that are "well beyond the purposes of the CSA." *Ibid.*

But as the court of appeals noted, "[w]ith a change of administrations came a change of perspectives." App. to Pet. for Cert. 8a. In 2001, then-Attorney General John Ashcroft sought an opinion from the Office of Legal Counsel (OLC) in the U.S. Department of Justice about whether a prescription issued under the DWDA is a valid prescription under the CSA and its implementing regulations. The opinion concluded that "assisting in suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04(a) that would justify a physician's dispensing controlled substances." App. to Pet. for Cert. 114a.

Relying on the OLC opinion and a regulation providing that a prescription for a controlled substance is "effective" only if issued for a "legitimate medical purpose," 21 C.F.R. § 1306.04, then-Attorney General Ashcroft issued a directive (Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607; App. to Pet. for Cert. 100a-05a) (directive), in which he concluded that physicians who prescribe controlled substances to assist a patient to hasten his or her own impending death violate the CSA, making them subject to sanctions including criminal prosecution and loss of their ability to prescribe controlled substances.

The directive made clear that those conclusions applied regardless of whether state law authorized or permitted such use. App. to Pet. for Cert. 102a. The directive also instructed the Drug Enforcement Administration (DEA) to look to the required medical documentation and reporting requirements under the DWDA, which "should contain the information

necessary to determine whether those holding DEA registrations who assist suicides in accordance with Oregon law are prescribing federally controlled substances for that purpose in violation of the CSA as construed by this Memorandum and the attached OLC Opinion." *Id.* at 104a.

3. Seeking to protect its physicians, its ability to regulate the practice of medicine, and its sovereign ability to implement the will of Oregon's people by providing competent terminally ill adults with a right Oregonians twice voted to confer, Oregon brought suit in the United States District Court for the District of Oregon. The State asserted, in part, that the directive exceeded the U.S. Attorney General's authority because Congress did not authorize the U.S. Attorney General to override the States' right to regulate the practice of medicine. A doctor, a pharmacist, and several terminally ill Oregonians intervened.

The District Court agreed that nothing in the CSA supports the U.S. Attorney General's conclusion that Congress intended to substitute his judgment for the historic authority of the State to determine the scope of legitimate medical practice. Consequently, the court permanently enjoined enforcement of the directive.

The District Court began with this Court's opinion in *Washington v. Glucksberg*, 521 U.S. 702 (1997), which, the court noted, acknowledged the "earnest and profound debate" about end-of-life treatment occurring in the States. App. to Pet. for Cert. 66a-67a. Although the District Court agreed that the CSA gives the U.S. Attorney General and the DEA "broad authority to regulate controlled substances," the court concluded: "No provision of the CSA, however, alone (as defendants urge) or viewed as a 'symmetrical and coherent scheme' demonstrates or even suggests that Congress intended to delegate to the Attorney General or the DEA the authority to decide, as a matter of national policy, a question

of such magnitude as whether physician-assisted suicide constitutes a legitimate medical purpose or practice." App. to Pet. for Cert. 87a.

Nor could the court find support for the U.S. Attorney General's position in the legislative history of the CSA. Rather, that history overwhelmingly supported the conclusion "that Congress' intent was to address problems of drug abuse, drug trafficking, and diversion of drugs from legitimate channels to illegitimate channels." *Id.* at 89a-90a. Finally, the court noted that none of the cases on which the U.S. Attorney General relied involved doctors or pharmacists who were acting in compliance with state law. *Id.* at 92a-93a (citing, *inter alia*, *United States v. Moore*, 423 U.S. 122 (1975)). In concluding, the court stated: "The determination of what constitutes a legitimate medical practice or purpose traditionally has been left to the individual states. . . .The CSA was never intended, and the USDOJ and DEA were never authorized, to establish a national medical practice or act as a national medical board." App. to Pet. for Cert. 94a-95a.

Petitioners appealed, and the court of appeals affirmed. That court, too, began its analysis with *Glucksberg*. App. to Pet. for Cert. 9a. The court noted this Court's statement that determining whether to permit physicians to aid those who wished to hasten death "belongs among state lawmakers," *ibid.* (citing 521 U.S. at 735), in the "'laboratory' of the States." *Ibid.* (quoting 521 U.S. at 737 (O'Connor, J., concurring)). As the District Court had, the court of appeals explained that States bear, and historically have borne, primary responsibility for regulating medical care. App. to Pet. for Cert. 10a. Therefore, unless the federal statute in question is "unmistakably clear," the courts will not conclude that Congress intended to alter that federal balance. *Id.* at 11a. And as the District Court did, the appeals court concluded that "Congress has provided no indication—much less an

'unmistakably clear' indication—that it intended to authorize the Attorney General to regulate" the practice of medicine in this context. *Id.* at 12a. The court of appeals' review of the legislative history confirmed that Congress was concerned with drug abuse, drug addiction, and the diversion of controlled substances out of legitimate channels, not with substituting the U.S. Attorney General's judgment for that of state regulators. *Id.* at 18a-20a. Because Congress had not expressed its clear intention to replace the States as the regulators of medical practice, the court concluded that it was "under no obligation to defer to the Attorney General's interpretation of his role under the statute and its implementing regulations." *Id.* at 21a.

The dissenting opinion concluded that the U.S. Attorney General's interpretation of the "legitimate medical purpose" regulation was valid and controlling. Generally rejecting the majority's analysis, the dissent determined that the CSA was not limited to combating drug abuse, App. to Pet. for Cert. 34a-36a; that Congress did not intend to preserve the States' traditional authority over the practice of medicine if that practice involved controlled substances, *id.* at 36a; and that the "clear statement" rule does not apply to the CSA, *id.* at 45a-47a. Ultimately, the dissent concluded that the directive was an interpretation of the agency's "legitimate medical purpose" regulation, not an interpretation of the CSA itself, *id.* at 54a, and it was therefore entitled to be judged under a "highly deferential standard of review," *id.* at 55a. Applying that standard, the dissent found the directive to be lawful and binding. *Id.* at 56a.

Summary of Argument

Congress enacted the CSA to prevent diversion of drugs out of legal channels and into illegal markets. As one means to that end, the Act divides controlled substances into those that have no accepted medical uses and those that do. Here,

petitioners have singled out a particular medical practice, one affirmatively authorized and regulated by state law, and insisted that no controlled substance, even those having accepted medical uses, may be used for that purpose even in the absence of evidence of diversion. That the U.S. Attorney General's action here is apparently unprecedented does not, by itself, mean that the CSA does not authorize the power petitioners claim. Nevertheless, petitioners can point to no explicit language in the CSA authorizing the U.S. Attorney General to outlaw particular medical practices involving drugs that admittedly have accepted medical uses. Indeed, nothing in the text or history of the CSA suggests that Congress intended to authorize a federal agent to override the States' historic power to regulate medical practice. As then-Attorney General Reno explained, the Act is "essentially silent" about "regulating the practice of medicine that involves legally available drugs." Or. Br. in Opp. Supp. App. 4. Petitioners must, therefore, rely on inherently ambiguous terms, such as "legitimate medical purpose" to support their claim of authority.

That failure to find explicit authority should be dispositive. This Court repeatedly has explained that the historic role of the States in the federal system demands special consideration. Where the traditional police powers of the States, such as regulating the practice of medicine, are at stake, the Court will find that Congress intended to displace the States only where the statute in question makes that intention unmistakable. Where that clear statement requirement applies, it is a condition precedent to the deference under *Chevron U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837 (1984), that the U.S. Attorney General claims.

The Court applies a similar and related rule of statutory construction when congressional action would push the limits of constitutional authority. While Congress may expressly

determine that particular drugs have no accepted uses, as it did with marijuana, Congress has neither made that determination about the drugs at issue here nor expressed the intention to transfer the regulation of medical practice from the States to the U.S. Attorney General. What the U.S. Attorney General seeks to regulate in this case is neither the commercial aspect of the interaction between doctor and patient, nor the amount of the drug that is prescribed; it is, rather, the intention of the parties to that transaction. While intent is significant in many contexts, the Court would have to break new constitutional ground to determine that the Commerce Clause power extends to regulating the doctor-patient relationship at that level.

Petitioners argue, incorrectly, that the clear statement requirement does not apply here, but they do not suggest that, if it does, the CSA contains such a statement. Because the language of the CSA does not demonstrate clearly that Congress intended to displace the States as the traditional regulators of medical practice or that it intended to authorize the U.S. Attorney General to push Congress's constitutional authority to the extent that would be required to sustain the claim made here, the Court's prudential rules require rejection of petitioners' argument.

ARGUMENT

This Court has acknowledged the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide" ongoing throughout the nation. *Glucksberg*, 521 U.S. at 735; *id.* at 737 (O'Connor, J., concurring) (same); *id.* at 738 (Stevens, J., concurring in the judgments) (same); *id.* at 753 (Souter, J., concurring in the judgment) (noting lack of unanimity about the practice, accepting representation that providing drugs to hasten death would be consistent with standards of medical practice in appropriate circumstances). *Glucksberg* also acknowledged

the gradual evolution of attitudes about physicians assisting dying people to end their lives, especially in light of modern reexamination of end-of-life care. *Id.* at 710-19. "Public concern and democratic action are therefore sharply focused on how best to protect dignity and independence at the end of life, with the result that there have been many significant changes in state laws and in the attitudes these laws reflect." *Id.* at 716.[4]

While *Glucksberg* was still in the courts, the people of Oregon took the controversial step that led to this litigation. Subject to the stringent limitations already described, they granted themselves the right to enlist the aid of physicians if they choose to end their own life rather than suffer the pain or the loss of control and dignity that often accompanies terminal illness.[5] Between 1998, when the DWDA was implemented, and 2004, the latest complete reporting period, 208 persons in Oregon died after ingesting a lethal dose of Schedule II controlled substances prescribed pursuant to that statute. Oregon Department of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act*, 20 (2005) (Seventh Annual Report).

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[4] The opinions in *Glucksberg* belie petitioners' claim that the medical practice authorized by the DWDA is subject to universal condemnation. *See* Pet. Br. 21-24. Oregon's disagreement with that claim is explicit in the DWDA itself. The brief of the patient intervenors describes the disagreement of others.

[5] In 2004, 87% of those who requested lethal prescriptions reported that they did so, at least in part, because they feared loss of control; 78% loss of dignity. Oregon Department of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act*, 15 (2005). The report can be found at http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf.

After congressional efforts to derail Oregon's experiment failed, the U.S. Attorney General issued his directive. The directive asserted that prescribing controlled substances for the purposes authorized by the DWDA would render a physician liable to lose the ability to prescribe controlled substances, *id.* at 102a, and asserted further that the DEA could and should obtain state records identifying those physicians who were implementing the Oregon law. *Id.* at 103a-104a. The OLC memorandum also noted the possibility of criminal prosecution. *Id.* at 112a. The threat was patent: physicians who prescribed controlled substances for the purposes authorized by the DWDA risked their ability to prescribe medication for their patients, which is equivalent to risking their professional lives, and they risked their freedom.

But as former Attorney General Reno, the District Court, and the court of appeals all concluded, the CSA contains scant support for the U.S. Attorney General's claim of authority to take those steps. "The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels." *Raich*, 125 S. Ct. at 2203 (footnotes omitted). "To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Id.*

Although Congress designed the CSA primarily to prevent diversion of drugs into illicit markets, neither the OLC analysis nor the U.S. Attorney General's directive suggested that drugs prescribed under the DWDA had been diverted into illicit markets, that the DWDA created a realistic possibility of diversion, or that, even if it did, the amounts in question could have any noticeable impact on the war on drugs. App.

to Pet. for Cert. 100a-148a. Nor does petitioners' brief address diversion.[6] In sum, neither diversion nor abuse of controlled substances, as those terms are defined in the CSA, is at issue in this case and petitioners are required to break new ground under the CSA by claiming authority not previously exercised by the U.S. Attorney General and not previously recognized by the courts.

While it is now settled that Congress can determine that certain drugs have no accepted medical uses and may punish their possession, *Raich*, the drugs at issue here are not the Schedule I drugs about which Congress has made that determination. They are, rather, Schedule II drugs, which do have accepted uses. Notwithstanding that the language and history of the CSA reveal no intent to displace state regulation of the reasons for which doctors may prescribe those admittedly useful drugs, the U.S. Attorney General claims that Congress mandated a uniform national standard for the prescriptions doctors may write for them, or at least empowered him to make a use-by-use, nationally binding

[6] Petitioners do repeat their conclusory assertion that taking drugs for the purposes authorized by the DWDA "*is* a form of 'drug abuse.'" Pet. Br. 45 (emphasis in original). But the particular drug abuse, as defined in the CSA, that Congress intended to prevent was that deriving from the drug's "stimulant, depressant or hallucinogenic effect on the central nervous system," 21 U.S.C. § 811(f). Although the drugs used under the DWDA are chosen for their "depressant . . . effect on the central nervous system," that is equally true of every prescription for those drugs, which are primarily used as sedatives and sleep aids. U.S. National Library of Medicine and National Institutes of Health, *Medline Plus*, http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202081.html (June 27, 2005).

determination of which prescriptions are legitimate. *See* Pet. Br. 29 (asserting that his decision about which particular uses are legitimate should be binding on the States).

To support their groundbreaking claims, petitioners assert that the CSA prohibits all uses of controlled substances that it does not authorize and authorizes doctors to prescribe those substances only for "legitimate medical purposes." Oregon could hardly disagree; that is what the Act states. But the issue in this case turns on whether, in the absence of diversion or abuse as those terms are defined in the CSA and without following any procedure specified in that Act, the U.S. Attorney General may simply overrule a State's determination about the validity or legitimacy of a medical practice. Petitioners are forced to base their claim of authority to take that step primarily on what Congress did not say. They reason that "[b]ecause nothing in the CSA . . . makes the definition of 'legitimate medical purpose' or 'treatment' depend upon state law, this Court's decisions in *Mississippi Band* [*of Choctaw Indians v. Holyfield*, 490 U.S. 30 (1989)] and similar cases mandate that those phrases be given uniform federal definitions and not vary from State to State." Pet. Br. 25.[7]

[7] In light of the central differences between the parties about the issues in this case, petitioners' reliance on *Mississippi Band* borders on ironic. There, the Court had no trouble discerning that the text of the statute at issue, its legislative history, and the hearings leading to its enactment all clearly demonstrated Congress's intent to displace state court jurisdiction over Indian children. 490 U.S. at 43-45. The Court's determination that Congress intended a uniform national definition of domicile flowed from that determination of manifest congressional intent, not from ambiguity or silence.

Petitioners' claim is wrong in the first instance because the CSA does not demonstrate the intent to create the national standard on which they rely. Rather, Congress demonstrated its intent to respect state laws governing medical practices and disclaimed the intent to displace state law—including the intent to permit the U.S. Attorney General to displace state law—except in the event of direct conflict between the CSA itself and state law, a conflict that is absent here.

Moreover, rules of statutory construction lead to a different conclusion than the one petitioners draw. Petitioners claim that because Congress did not make itself clear about the meaning of terms such as "legitimate medical purpose," the Court must either infer that a uniform federal standard was intended under *Mississippi Band* or defer to the U.S. Attorney General under *Chevron*. But this Court has refused to infer congressional intent to displace the States' historic police power from congressional silence or ambiguity, especially where doing so would push the limits of Congress's constitutional authority. *E.g.*, *Solid Waste Agency of Northern Cook Cty. v. Army Corps of Engineers*, 531 U.S. 159, 172-74 (2001). Rather, where historic state powers like the power to regulate medical practice are implicated, only a clear statement of congressional intent to displace those historic powers is sufficient. *Ibid.* And where, as here, a clear statement of congressional intent is required, that clear statement is a condition precedent for a successful claim to deference. *Ibid.*

I. The U.S. Attorney General's threatened action would nullify the DWDA.

Petitioners argue that the U.S. Attorney General's threatened action "[a]t most," would "frustrate the purposes" of the DWDA. Pet. Br. 43-44. That claim is asserted primarily in an effort to persuade the Court that principles applied when federal law preempts state law have no role in this case. *Ibid.*

But petitioners fail to acknowledge that the U.S. Attorney General's threatened actions would make the DWDA completely ineffective, and their reasons for not applying the presumption against preempting state law in this area of traditional state regulation are peculiarly unpersuasive.

A. The DWDA does not merely "decriminalize physician assisted suicide."

Petitioners attempt to diminish the DWDA by describing it as merely "decriminalizing assisted suicide." Pet. Br. 13. That characterization says both too much and too little. It says too much because aiding another to commit suicide remains a crime in Oregon under most circumstances. Or. Rev. Stat. § 163.125(1)(b). And even those physicians who provide a prescription to enable a person to end his or her own life and those pharmacists who fill that prescription may not give any physical assistance to the patient if the patient chooses to take the drugs. More importantly, petitioners' description says too little because it fails to acknowledge that the people of Oregon have made an affirmative policy choice to grant themselves and their loved ones the right to avoid the intractable pain or the loss of control and dignity that accompany some forms of fatal disease. In making that choice, Oregon has not merely taken hands off. It has, rather, enacted a comprehensive set of regulations intended to ensure that only terminally ill persons with less than six months' expected lifespan who are capable of making a competent and informed choice may receive drugs, with the concurrence of at least two physicians, to hasten death. In short, the DWDA does not merely "decriminalize assisting suicide," it regulates and limits that practice.

Petitioners also claim that physicians could use other methods of aiding patients to hasten death. Pet. Br. 44. In rejecting that same argument, the court of appeals found it clear that controlled substances are "the best and most reliable

means for terminally ill patients to painlessly take their own lives." App. to Pet. for Cert. 8a n. 5. Participating Oregon doctors unanimously agree; all doctors who have aided patients under the DWDA have prescribed Schedule II controlled substances. Seventh Annual Report, at 14. Even if some other method or drug might work, preventing Oregon physicians from using the most effective and humane means of easing death, the means chosen in every case by every physician, would make the law largely ineffective by making the ability to provide a quick, sure, and painless death speculative at best.

As the court of appeals also noted, the provision of the CSA on which the U.S. Attorney General relies for his claim of authority is not limited by its terms to conduct involving controlled substances. App. to Pet. for Cert. 8a n. 5. That section permits the U.S. Attorney General to deregister physicians whose conduct is "inconsistent with the public interest." 21 U.S.C. § 824(a)(4). The terms of that section do not require that the conduct leading to deregistration be connected with controlled substances. If the U.S. Attorney General can deregister a physician who prescribes controlled substances in the manner permitted by the DWDA in the absence of any evidence of diversion because he concludes that doing so is "inconsistent with the public interest," he can deregister any physician who provides similar medical aid to a terminally ill patient, notwithstanding that the aid does not involve the use of controlled substances. In light of the obvious reality that no physician can afford to risk the ability to prescribe medicine for his or her patients, the breadth of power petitioners claim is nothing less than the power to prevent the operation of the DWDA in its entirety.

B. The principles underlying the presumption against preemption apply here.

Petitioners assert that the U.S. Attorney General's directive would not "invalidate" the DWDA. Pet. Br. 43; *citing California Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 280 (1987)). And they stress that the DWDA retains its "undeniable effects on state law." Pet. Br. 44. But they draw the wrong conclusion—that the presumption against preemption is inapposite, Pet. Br. 43—from those assertions. First, although petitioners are correct that the DWDA would continue to shield physicians from state prosecution, that shield would be meaningless if no physician would dare risk federal prosecution or deregistration. More significantly, enactment of federal criminal laws does not "invalidate" state criminal laws aimed at the same conduct, in that that conduct may still be prosecuted in the state courts. Nevertheless, this Court applies the same clear statement requirement when determining whether federal criminal laws apply to crimes traditionally prosecuted by the States. "'[U]nless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance' in the prosecution of crimes." *Jones v. United States*, 529 U.S. 848, 858 (2000) (quoting *United States v. Bass*, 404 U.S. 336, 349 (1971)). *See id.* at 859-60 (Stevens, J., concurring) (noting the "kinship" between the presumption against preemption, the Court's reluctance to believe that Congress intended to intervene in criminal law, a matter of traditional state governance, and the clear statement requirement).

Consequently, even if it were technically accurate to describe what the U.S. Attorney General seeks to do here as something other than "preemption," it is difficult to see why different principles would govern total frustration of state laws. *Department of Revenue of Ore.* v. *ACF Industries, Inc.*, 510 U.S. 332, 345 (1994) (applying presumption against

preemption when "determining the breadth of a federal statute that *impinges upon or* pre-empts the States' traditional powers"; *citing Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 533 (1992) (emphasis added). The U.S. Attorney General's threats will prevent state law from operating as state lawmakers intended. The affront to the State's sovereignty is the same in kind, even if not necessarily in degree, as it would be if he were able simply to declare the DWDA invalid.

II. The CSA does not itself prohibit the uses of controlled substances permitted by the DWDA, and it does not authorize the U.S. Attorney General to do so.

A. Neither the text of the CSA nor judicial interpretations of that text suggest that Congress intended to displace the States' traditional power to regulate medical practice, even when controlled substances are involved.

1. The text generally and judicial interpretations

Petitioners contend that the text of the CSA demonstrates that Congress itself prohibited use of controlled substances for the purposes specified in the DWDA or, at a minimum, delegated to the U.S. Attorney General the authority to prohibit those uses. They argue that this conclusion follows from the CSA's prohibition on prescribing controlled substances except for a "legitimate medical purpose" and in the "usual course of professional treatment," a prohibition they describe as "central" to the "comprehensive national scheme Congress established to regulate controlled substances." Pet. Br. at 14.

What is "central" to the CSA is the "closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. §§ 841(a)(1),

844(a)." *Raich*, 125 S. Ct. at 2203. *Moore* explains that Congress intended that closed system to prevent diversion of controlled substances outside of "the legitimate distribution chain." 423 U.S. at 141. Whether conduct violated the CSA "was intended to turn on whether the 'transaction' falls within or without legitimate channels." *Id.* at 135. The federal registration system "contemplates that [the physician] is authorized by the state to practice medicine and to dispense drugs in connection with his professional practice." *Id.* at 141. This Court agreed that the CSA authorized Dr. Moore's conviction in large measure because the evidence was sufficient to demonstrate that he "acted as a large-scale 'pusher' – not as a physician." *Id.* at 143.[8]

Consistent with *Moore*, lower federal courts have enforced the CSA by assessing whether the transaction at issue in a particular case amounts to diversion outside legitimate channels of distribution. The Fifth Circuit, for example was "able to glean from reported cases" nine factors that would support a finding that the physician had engaged in transactions that were prohibited by the CSA. *United States v. Rosen*, 582 F.2d 1032, 1035-36 (5th Cir. 1978) (identifying factors tending to show that physicians were acting as "pushers," such as prescribing inordinately large amounts of controlled substances and issuing large numbers of prescriptions for them). Other courts of appeal have followed a similar approach. *E.g.*, *Humphreys v. Drug Enforcement Admin.*, 96 F.3d 658, 666 (3rd Cir. 1996) (vacating DEA's decision to revoke a physician's registration because the

[8] The Court noted that the jury made that finding after being instructed that Dr. Moore could not be convicted if he merely made an honest effort to dispense drugs "in compliance with an accepted standard of medical practice." *Id.* at 142 n. 20.

evidence proffered by DEA showed that "the potential for diversion is so unlikely as to be unsustainable"); *United States v. Rosenberg*, 515 F.2d 190, 197, 199 (9th Cir.), *cert. denied*, 423 U.S. 1031 (1975) (affirming doctor's conviction where the jury was instructed that doctor violated the CSA if he "was not acting in good faith as a doctor, but simply pushing pills"). The issue consistently has been whether the defendant was acting as a "pusher"—dispensing drugs outside the CSA's "closed system"—rather than acting as a physician. Juries typically make that determination based on the circumstances of each case. "In making a medical judgment concerning the right treatment for an individual patient, physicians require a certain latitude of available options. *Doe v. Bolton*, 410 U.S. 179 (1973). Hence, '[w]hat constitutes *bona fide* medical practice must be determined upon consideration of evidence and attending circumstances.' *Linder v. United States*, [268 U.S. 5, 18 (1925)]." *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973).

Oregon has found no previous instance in which the U.S. Attorney General interpreted the CSA to authorize prosecution or deregistration of physicians for conduct having no nexus to diversion.[9] Nor has it found evidence that, before this case, anyone interpreted these provisions to authorize the

[9] To their credit, petitioners do not claim that prescribing drugs for the purposes authorized by the DWDA creates any greater risk of diversion of drugs than would occur with any other prescription for those same drugs. Indeed, petitioners have not shown that any illicit market for those drugs exists. *See* OLC Memo, App. to Pet. for Cert. 106a-148a. That memo strongly suggests what should be apparent in any event: the U.S. Attorney General's action here has always been focused on Oregon's policy choice, not on the controlled substances used to implement that choice.

U.S. Attorney General to single out a particular medical practice and determine that no controlled substances may be used for that practice.

That former restraint was consistent with the limited authority the CSA grants the U.S. Attorney General. Textual references to "legitimate medical purpose" and the "usual course of professional practice" reveal that Congress intended to delegate limited factfinding—not broad policymaking—authority to the U.S. Attorney General in respect to the scheduling and use of controlled substances. The U.S. Attorney General's scheduling authority, for example, gives him authority to list a substance on a CSA schedule only if he "finds" that it has a potential for abuse and "makes . . . the findings" specified in the CSA. 21 U.S.C. § 811(a)(1)(A) and (B). Although petitioners claim that the U.S. Attorney General could simply move the drugs used under the DWDA to Schedule I, then move them back to Schedule II with restrictions, Pet. Br. 30, that overstates his authority. Except when making temporary changes, *see Touby*, 500 U.S. at 163, the U.S. Attorney General must obtain the Secretary's agreement to schedule any previously unscheduled drugs or to change the schedule in which a drug has been placed. 21 U.S.C. § 811(a) and (b).[10] "This explicit delegation of

[10] Pointing to a Medicare manual, Pet. Br. 47 n. 18, petitioners assert that there is "no conflict" between the U.S. Attorney General's views and those of the Secretary. Assuming that manual has any application to the question before the Court, the process specified in the CSA requires more than an absence of conflict; it requires the Secretary to make a medical and scientific evaluation and it requires the U.S. Attorney General to engage in specifically defined hearings to allow comment on the medical and scientific evidence. None of that happened here.

authority to *apply* prescribed statutory criteria is not equivalent to an explicit delegation of authority to *define* those criteria." *Grinspoon v. Drug Enforcement Admin.*, 828 F.2d 881, 885 n. 5 (1st Cir. 1987) (emphasis in original).

Thus, when petitioners assert that the U.S. Attorney General's authority to determine whether "a *particular* use" of a controlled substance is permissible should be no less binding than his decision that a substance has no accepted medical use, Pet. Br. 29 (emphasis in original), they understate the authority they claim. To schedule or reschedule a drug, the U.S. Attorney General must obtain the Secretary's approval and follow specified procedures. Because he did none of those things here, petitioners necessarily are claiming that the U.S. Attorney General may identify particular medical practices to which no otherwise approved controlled substances may be put, and that he may do so without obtaining medical and scientific approval from the Secretary, without notice or hearing, and without following any congressionally specified process.[11]

[11] Some Schedule II drugs have "a currently accepted medical use with severe restrictions." 21 U.S.C. § 812(b)(2)(B). That suggests that the U.S. Attorney General, following specified procedures and with the concurrence of the Secretary, could impose limits on individual drugs. To accomplish the goal identified in the directive, however, he would have to take that step for each and every controlled substance or, at least, all that are capable of causing a swift, sure, and painless death. The CSA contains no textual or historic support for the proposition that Congress intended to authorize anything of that sort. And in any event, that is not what he attempted here. Rather, he has focused on a specific medical practice and determined that no controlled substance may be used for that purpose, something about which the

2. The "anti-preemption clause"

The text of the CSA shows that Congress did not intend to grant the U.S. Attorney General the regulatory authority claimed here. In every preemption case, the purpose of Congress is "the ultimate touchstone." *Medtronic Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). Here, the text contains a clear expression of Congress's intention not to displace any more state law than absolutely necessary. 21 U.S.C. § 903 provides:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

When Congress has intended to authorize agencies to enact rules or regulations that would preempt state law, it has said so expressly. *E.g.*, 7 U.S.C. § 2156(h).[12] That Congress knows

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CSA is simply silent. And, of course, he followed no specified procedures and did not obtain the agreement of the Secretary.

[12] That section provides:

> The provisions of this chapter shall not supersede or otherwise invalidate any such State, local, or municipal legislation or ordinance relating to animal fighting ventures

how to authorize agencies to preempt state law and did not do that here demonstrates that Congress intended to supersede only state laws that conflict with the terms of the CSA itself, not with regulatory interpretations. *See, e.g., Argentine Republic v. Amerada Hess Shipping*, 488 U.S. 428, 440 (1989) (when it wants to, Congress knows how to include the high seas within statute's jurisdictional reach, citing examples; failure to do so invokes the canon of construction that legislation applies only within territorial United States); *NLRB v. Action Automotive, Inc.*, 469 U.S. 490, 497 (1985) (similar). It follows, therefore, that petitioners should not be able to rely on the U.S. Attorney General's regulations to support their claim. Rather, they should have to demonstrate a positive conflict between the DWDA and the text of the CSA itself.

B. The CSA contains no clear statement of intent to displace state regulation of medicine.

In rejecting petitioners' arguments, the court of appeals relied heavily on the absence of a clear statement of congressional intent to displace the States as the regulators of medical practices. App. to Pet. for Cert. 11a-13a. The requirement of a clear statement serves separate goals depending on whether it is invoked to protect historic state powers or to implement the Court's prudential reluctance to

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> except in case of a direct and irreconcilable conflict between any requirements thereunder and this chapter *or any rule, regulation, or standard hereunder*.

(Emphasis added). Other anti-preemption provisions similarly refer to conflicts with the statute or with rules, regulations, or orders enacted to carry out the statute's purposes. *E.g.*, 15 U.S.C. § 78bb(a); 30 U.S.C. § 955(a).

reach constitutional issues needlessly. Where one construction of a statute would impinge upon traditional state regulatory powers, the Court's insistence on finding unmistakable evidence of Congress's intent protects state sovereignty; and where one construction would call upon the Court to decide difficult and sensitive constitutional questions, a clear statement ensures that the Court is not forced to decide them unnecessarily. *Solid Waste Agency*, 531 U.S. at 172-74.

Particularly where, as here, the constitutional question implicates the Commerce Clause, those goals may overlap or even converge. In some cases, the States must depend upon their representatives in Congress to protect their prerogatives when Congress exercises its commerce powers. *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528 (1985). For that reason, the Court is careful to ensure that the political process on which the States must rely has been given an opportunity to work. That can happen only if the text of a proposed law clearly informs members of Congress that their vote could impinge upon the existing powers or rights of the States themselves or of individual constituents. Consequently, the Court must be "absolutely certain that Congress intended" that result. *Gregory v. Ashcroft*, 501 U.S. 452, 464 (1991). "'[T]o give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests.'" *Id.* (quoting L. Tribe, *American Constitutional Law* § 6-25, p 480 (2d ed. 1988) (brackets by the Court; emphasis in original)).

Similar reasons support the clear statement rule when congressional action would intrude upon "the historic powers of the States, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)....'In traditionally sensitive areas, such as legislation affecting the federal balance, the requirement of [a] clear statement assures that the legislature has in fact

faced, and intended to bring into issue, the critical matters involved in the judicial decision.'" *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 65 (1989) (quoting *Bass*, 404 U.S. at 349). The presumption against preemption of State laws "provides assurance that the federal-state balance will not be disturbed unintentionally by Congress, or unnecessarily by the courts." *Gade v. National Solid Wastes Management Ass'n.*, 505 U.S. 88, 116 (1992) (Souter, J., dissenting) (citation and internal quotation marks omitted). Consequently, whether the issue is the historic powers of the States or the extent of Congress's commerce power, the clear statement rule ensures that the States' prerogatives are not displaced by accident or inadvertence.

That caution on the Court's part serves, among other things, to maintain the division of powers between the state and federal governments embodied in the federal structure. That division was, of course, an essential part of the founders' design, and one of our nation's "first principles." *United States v. Lopez*, 514 U.S. 549, 552 (1995). "'The powers delegated by the proposed Constitution to the federal government are few and defined. Those which are to remain with the States are numerous and indefinite.'" *Ibid.* (quoting The Federalist No. 45, pp. 292-293 (James Madison) (C. Rossiter ed. 1961)).

But the benefits of federalism are not merely quaint relics of simpler days, trotted out from time to time to placate parochial interests. This Court has recently and repeatedly reaffirmed the importance of the state-federal balance as a bulwark against the excessive aggregation of power in either state or federal government. "Just as the separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power in any one branch, a healthy balance of power between the States and the Federal Government will reduce the risk of

tyranny and abuse from either front." *Gregory*, 501 U.S. at 458. Thus, the "constitutionally mandated division of authority was adopted by the Framers to ensure protection of our fundamental liberties." *Lopez*, 514 U.S. at 552 (citation and internal quotation marks omitted). The clear statement rule helps defend that division of authority and is "an acknowledgement that the States retain substantial powers under our constitutional scheme, powers with which Congress does not readily interfere." *Gregory*, 501 U.S. at 461.

Petitioners take a parsimonious view of both the Court's insistence on protecting state sovereignty and the clear statement rule implementing that protection. They claim that the U.S. Attorney General's interpretation is entitled to *Chevron* deference. They assert that the clear statement rule is narrowly limited, applying only to federal statutes that implicate the heart of state sovereignty. Pet. Br. 38. And they argue that giving any consideration to state law would turn the Supremacy Clause "on its head." *Id.* at 44 and n. 17.

1. Because the U.S. Attorney General's action here would displace traditional state authority, a clear statement is a condition precedent to that action or to *Chevron* deference.

This Court will not impute to Congress the intent to alter the usual state-federal balance or push the limits of congressional power unless the text of the statute in question makes that intent unmistakable. *Solid Waste Agency*, 531 U.S. at 172-74; *Jones*, 529 U.S. at 858-59. Administrative authority to displace state authority in areas historically regulated by the States must likewise be supported by clear statutory language. *Solid Waste Agency*, 531 U.S. at 172 (citing *Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council*, 485 U.S. 568, 575 (1988)); *Hillsborough County v. Automated Medical Labs.*, 471 U.S. 707, 715-16 (1985); *see also FDA v. Brown &*

Williamson Tobacco Corp., 529 U.S. 120, 125 (2000) ("Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'") (quoting *ETSI Pipeline Project v. Missouri*, 484 U.S. 495, 517 (1988)).[13] Consequently, the U.S. Attorney General's claim to deference in applying the CSA here must surmount the "clear statement" hurdle because it impinges upon the DWDA at the margins of Congress's powers under the Commerce Clause.

2. The clear statement rule applies more broadly than petitioners acknowledge.

Petitioners' discussion of the clear statement rule focuses almost exclusively on *Gregory*, on which the court of appeals relied. Petitioners chide the lower court for that reliance, asserting that *Gregory* applies only where federal law "would encroach upon how a State defines itself as a Sovereign." Pet. Br. 38 (internal quotation marks omitted).

Gregory itself suggests that the rule it applied extends beyond the structural-sovereignty limits petitioners seek to

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[13] *Chevron* has been described as establishing a "two-step procedure for evaluating whether an agency's interpretation of a statute is lawful." *National Cable & Telecommunications Assn. v. Brand X Internet Services*, 545 U.S. ___, ___ (June 27, 2005) (slip op. at 14); *accord Brown & Williamson Tobacco Corp.*, 529 U.S. at 132. Some commentators call the preliminary step—determining whether a clear statement is needed in particular cases—"step zero." Cass R. Sunstein, *Chevron Step Zero*, 92 Va. L. Rev. (forthcoming April 2006) (available at http://ssrn.com/abstract=739129; last visited June 29, 2005); Thomas W. Merrill & Kristin E. Hickman, *Chevron's Domain*, 89 Geo. L. J. 833, 873 (2001).

impose. In discussing the "delicate balance" of federalism, the Court recognized that the Supremacy Clause allows Congress to legislate in "areas" traditionally regulated by the States, "a power that we must assume Congress does not exercise lightly." 501 U.S. at 460. To be sure, the Court noted that the issue in *Gregory* itself went "beyond an area traditionally regulated by the States" to touch upon matters "of the most fundamental sort for a sovereign entity." *Id.* While those fundamental matters unquestionably added weight to the state interest involved, the Court did not suggest that *only* matters "fundamental" to a State's identity as a sovereign are sufficient to invoke the respect to which State sovereignty is entitled or the clear statement rule that serves to protect that interest. To the contrary, in endorsing and applying the clear statement rule, *Gregory* cited *Bass*, which addresses the States' traditional authority over criminal law, and *Rice*, which dealt with regulation of grain storage elevators. 501 U.S. at 461.

And the Court subsequently has suggested a broader view of *Gregory* than petitioners acknowledge. In *Raygor v. Regents of the University of Minnesota*, 534 U.S. 533, 543-44 (2002), the Court relied on *Gregory* to support its holding that a clear statement was needed to demonstrate congressional intent to extend the statute of limitations for a federal claim against a State in the State's courts. Even if extending the statute of limitations did not necessarily abrogate the States' sovereign immunity, it "at least affects the federal balance in an area that has been a historic power of the States[.]" *Raygor*, 534 U.S. at 544. *See also United States v. Morrison*, 529 U.S. 598, 662-63 (2000) (Breyer, J., dissenting) (*Gregory* insists upon a "'plain statement' of legislative intent when Congress legislates 'in areas traditionally regulated by the States.'"); *Lopez*, 514 U.S. at 611 (Souter, J., dissenting) (clear statement rule applies "in cases implicating Congress's

historical reluctance to trench on state legislative prerogatives or to enter into spheres already occupied by the States," citing *Gregory*).[14]

Even if *Gregory* were as limited as petitioners contend, it is neither the first nor the only case to establish that the Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice*, 331 U.S. at 230. As noted above, *Rice* dealt with regulation of grain storage elevators, *id.* at 220-21, a subject obviously not central to how a State defines itself as a sovereign. Other cases apply the clear statement rule in areas equally far from the structure of sovereignty. *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 365 (2002) (state regulation of insurance not to be superseded by federal law "unless that was the clear and manifest intent of Congress"); *Jones*, 529 U.S. at 857 ("unless Congress conveys its purpose clearly, it will not be deemed to have changed the federal-state balance in the prosecution of crimes") (internal quotation marks and citation omitted); *California Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997) (state wage-claim laws presumed not to be preempted unless contrary result was "the clear and manifest purpose of Congress"); *Hisquierdo v. Hisquierdo*, 439 U.S. 572, 581 (1979) (state regulation of family law will not be overridden

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[14] In addition, the Court repeatedly has relied on *Gregory*'s description of the federalism principles that underlie the clear statement rule. *E.g.*, *Morrison*, 529 U.S. at 616 n. 7; *Lopez*, 514 U.S. at 552; *id.* at 576 (Kennedy, J., concurring); *id.* at 584 (Thomas, J., concurring); *New York v. United States*, 505 U.S. 144, 163, 182-83 (1992).

unless that result is "positively required by direct enactment").[15]

Thus, while *Gregory* may describe the clear statement rule most plainly and explain the historic and constitutional reasons for its existence and application most vividly, that case is far from standing alone in demanding application of the rule where traditional state powers—not only matters going to the heart of state sovereignty—are at stake. Consequently, petitioners' assertions that the court of appeals drastically extended the clear statement rule and that there is "no basis in this Court's precedents" for its application to this case, Pet. Br. 37, run counter to well-settled principles.

3. The CSA reflects Congress's intent to respect the States' traditional role in regulating medical practice.

Petitioners argue that Congress intended the CSA to apply uniformly nationwide and that any consideration of state law would upset that congressional design and be contrary to the presumption of uniform nationwide application. *See* Pet. Br.

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[15] Noting the breadth of the States' traditional powers, petitioners caution that application of the clear statement rule here "would mean that virtually every federal regulation would need a clear statement from Congress." Pet. Br. 39. First, of course, clarity is not generally considered a bad thing in legislative enactments. But whatever might be the outer limits of the sphere of state functions that call for a clear Congressional statement, as described in the text, pp. 38-41, the Court's cases already demonstrate that the States' regulation of the health, welfare, and comfort of their citizens falls at or near its core. Thus, the Court need neither break new ground nor define the boundaries of the clear statement rule to recognize that it applies here.

25 (citing *Mississippi Band*). To be sure, the CSA reflects a congressional conclusion that controlled substances are a matter of national concern. But that does not mean Congress intended to federalize every prescription of every controlled substance or to supplant all state laws on the subject. *Hillsborough County*, 471 U.S. at 717. "[E]very subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law." *Id.* at 719. Congress certainly can and sometimes does choose to defer to state law. *Rice*, 331 U.S. at 222-23 (explaining that Congress did as much); *Mississippi Band*, 490 U.S. at 43 ("Congress sometimes intends that a statutory term be given content by the application of state law."); *see also Geier v. American Honda Motor Co.*, 529 U.S. 861, 872 (2000) (acknowledging congressional power to mandate a "complex type of federal/state relationship" that would tolerate a conflict with ordinary preemption principles).

The text of the CSA demonstrates Congress's intent to give substantial deference to state laws. First, the disclaimer of intent to preempt state law in section 903 is plainly inconsistent with unyielding insistence on national uniformity. Second, because Congress stated that it did not intend to displace state laws "including" criminal penalties, it follows that Congress did not intend to limit the States to imposing more stringent criminal penalties. Rather, Congress necessarily intended to respect state laws that differed in other ways from the CSA.

Moreover, when Congress first enacted the CSA and when the U.S. Attorney General promulgated the "legitimate medical purpose" regulation on which he relies, 21 C.F.R. § 1306.04(a) (1971), the CSA expressly required the U.S. Attorney General to defer to state regulators and register any physician licensed by a State to dispense controlled

substances. 21 U.S.C. § 821(f) (1970). "'[R]egistration would be as a matter of right where the individual or firm is engaged in *activities* involving these drugs which are authorized or permitted under State law . . . .'" *Moore*, 423 U.S. at 141 n. 19 (quoting H.R. Rep. No. 91-1444, p. 23 (1970); emphasis and ellipses by the Court). Consequently, at the time the "legitimate medical purpose" regulation was enacted, it necessarily was true that, for purposes of determining whether a practitioner was entitled to registration, both Congress and the U.S. Attorney General intended to leave the definition of what medical purposes were "legitimate" to the States, whose laws, of course, vary.

Congress later amended the Act to permit the U.S. Attorney General to deregister a physician if he determined that registration was "inconsistent with the public interest." 21 U.S.C. § 824(a)(4) (1984). Determining whether registration is in the public interest "shall" be based on five factors, including the recommendation of State authorities. 21 U.S.C. § 823(f).[16] Indeed, of the five factors, three (nos. 1, 3, and 4)

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[16] The factors are:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
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> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
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> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

expressly require the U.S. Attorney General to consider state law, the actions of state regulators, or both. As the court of appeals explained, the 1984 amendments to this section were intended only to permit the U.S. Attorney General to act when state regulators proved ineffective in enforcing state laws. App. to Pet. for Cert. 19a-20a.[17] The court of appeals also correctly explained that Congress specifically intended the U.S. Attorney General to "continue to give deference to the opinions of the State licensing authorities." *Id.* at 20a (quoting S. Rep. No. 98-225 at 267, 1984 U.S.C.C.A.N. at 3449). But petitioners appear to read the "public health and safety" factor as a license to ignore the other four in favor of the "uniform

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[17] Both the House and the Senate acknowledged that the provision governing registration of state-licensed practitioners was changed because state licensing agencies were unable to ensure that all practitioners who were diverting drugs were investigated and disciplined by the states.

> [B]ecause of a variety of legal, organizational, and resource problems, many States are unable to take effective or prompt action against violating registrants. Since State revocation of a practitioner's license or registration is a primary basis on which Federal registration may be revoked or denied, problems at the State regulatory level have had a severe adverse impact on Federal anti-diversion efforts.

S. Rep. No. 98-225, at 266 (1984), 1984 U.S.C.C.A.N. 3182, 3448 (citation omitted); H.R. Rep. No. 98-835, Part I, at 7-8 (similar).

national standard," Pet. Br. 25, on which they insist. *Cf. ACF Industries*, 510 U.S. at 340 (a statute should be interpreted so as not to render one part inoperative). Nothing in the language or history of the Act, including the 1984 amendments, suggests that Congress ever intended to permit the U.S. Attorney General to deregister or prosecute a physician who acted in accordance with affirmative state law and in the absence of any evidence of diversion or drug abuse as that abuse is defined in the Act.

C. A clear statement is required here to support the U.S. Attorney General's threat to displace the States' traditional regulation of medical practice.

That the clear statement rule applies to protect the States' historic primacy in matters of health and medicine should be indisputable. "It is, of course, well settled that the State has broad police powers in regulating the administration of drugs by the health professions." *Whalen v. Roe*, 429 U.S. 589, 603 n. 30 (1977) (citing cases). The Court not only has described the regulation of health care as within the scope of the States' traditional powers, it expressly has concluded that a clear statement is required before the Court will conclude that Congress intended to interfere with that power. *Medtronic Inc.*, 518 U.S. at 475; *Hillsborough County*, 471 U.S. at 715. In *Medtronic*, the Court relied on the States' status as "independent sovereigns in our federal system" to conclude not only that a clear statement of preemptive intent was necessary to displace state law regulating the practice of medicine, but also to support a narrow interpretation of a provision expressly preempting state law. 518 U.S. at 485. The CSA, of course, contains an unambiguous expression of intent *not* to preempt state law.

Petitioners note that Congress has regulated many aspects of health care. Pet. Br. 42-43 (citing *Medtronic*). They contend that application of the clear statement rule here

threatens uniform application of the federal laws doing so, although they may also mean to imply that Congress has enacted so many laws addressing health and health care that the States' historic power to regulate medical care has been displaced in some way or to some degree. The difficulty with either of those arguments is that the case on which they rely not only acknowledges the Federal Government's "increasingly significant role in the protection of the health of our people," *Medtronic*, 518 U.S. at 475, but also holds that the clear statement rule and the presumption against preemption apply because of "federalism concerns and the historic primacy of state regulation of matters of health and safety." *Id.* at 485.

Petitioners also argue that Oregon is not exercising its police power here. First, they contend that aid in dying is incompatible with medicine, or at least a dictionary definition of medicine, because it does not aim to restore the patient to health. *E.g.*, Pet. Br. 11, 18-20. They also contend that the DWDA cannot be within the States' traditional powers because "there *is* no tradition of State[s] authorizing physician-assisted suicide." Pet. Br. 39 (emphasis in original). But those claims take an unjustifiably crabbed view of the States' sovereignty and of their role in the federal structure.

The claim that assistance in dying is not medical treatment proves too much. Petitioners rely on dictionary definitions of medicine that include "the . . . alleviation . . . of disease." Pet. Br. 19. And they expressly exclude from the reach of the directive the palliative provision of controlled substances to alleviate pain even where the physician knows that those substances will "haste[n] the patient's death." *Id.* at 20 n. 7. Thus, the disagreement between the parties may reduce to how narrowly petitioners define "alleviation" or, more precisely, who gets to decide what degree of alleviation is within the bounds of patient care.

This Court has acknowledged that technological means of extending life, including artificial administration of food and water, are forms of medical treatment. *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 278 (1990); *id.* at 287 (O'Connor, J., concurring); *id.* at 331 (Stevens, J., dissenting). Removal of those artificial means is necessarily also within the scope of medical practice. And that removal is no less intended to end the life of the patient, a life that could be prolonged indefinitely in some cases, than is the provision of the drugs at issue here. *Glucksberg*, 521 U.S. at 743 (Stevens, J., concurring in the judgment). The same is true of "do not resuscitate" orders. While a line surely can be drawn between those procedures and the one at issue here, *Vacco v. Quill*, 521 U.S. 793, 800-05 (1997), that line is not properly drawn on the basis of what is and is not "medical."

Petitioners' assertion that assisting suicide is not "traditional" is focused at the wrong level of generality. This Court has not suggested that the States' historic regulatory powers are limited to doing only that which they have done at some indeterminate past time or that the proper inquiry is whether the specific case, matter, or practice at issue is within the States' historic powers. Rather, the Court consistently has protected state prerogatives in "traditionally sensitive *areas*." *Will*, 491 U.S. at 65 (emphasis added). Regulating the practice of medicine is one of those areas. And history has vindicated the recognition that "a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting); *accord Glucksberg*, 521 U.S. at 737 (O'Connor, J., concurring). The U.S. Attorney General's claim that everything new is not within the scope of the States' traditional powers would reduce that laboratory to a one-way ratchet in which the States could regulate more

stringently, but never stray beyond orthodoxy in any area upon which federal law touches.

Perhaps more significant than either of those considerations, however, is the simple fact of state sovereignty itself. This Court's consistent recognition that States "primarily and historically" have power "to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons," *Medtronic*, 518 U.S. at 475 (citing cases), necessarily acknowledges that States have the sovereign's prerogative to determine what medical practices are and are not acceptable. None of the language Congress used in the CSA demonstrates unmistakably that Congress intended to reverse that longstanding recognition. To the contrary, the clues to legislative intent described above make it more likely that Congress intended to respect the States' sovereignty over the practice of medicine.

In *Raich*, of course, Congress unambiguously expressed its intention by placing marijuana on Schedule I. Here, by contrast, petitioners do not identify language in the CSA that clearly or unmistakably regulates or authorizes regulation of the specific practice permitted by the DWDA, of specific uses of any approved drug, or of specific medical practices. Rather, the statutory terms on which petitioners rely to support the claimed authority—"conduct which may threaten the public health and safety," "legitimate medical purpose," and "usual course of professional treatment"—are so elastic that accepting petitioners' construction would mean, as petitioners appear to embrace, that the Act permits the U.S. Attorney General to ban any particular use of any scheduled drug, Pet. Br. 29, and, apparently, to identify any disfavored medical practice and declare that no scheduled drug could be used for that purpose. And he can do so, they assert, without following any procedure or obtaining any scientific or medical input from the Secretary or anyone else. If that overstates the power

petitioners claim, they have not identified the principles that might limit it.

The DWDA is an expression of Oregon's "independent sovereign[ty]," *Medtronic*, 518 U.S. at 485, within the ambit of the State's historic power to regulate the practice of medicine. The U.S. Attorney General's threat to deregister or prosecute Oregon physicians and pharmacists who comply with the DWDA will necessarily deprive Oregonians of the rights embodied in that Act. Notwithstanding whether the U.S. Attorney General's threat is labeled as "preempting" the DWDA, it impinges on Oregon's exercise of its sovereignty in an area historically entrusted to the States. This Court unambiguously has refused to sanction similar federal action unless and until it has satisfied itself that Congress intended that result by including a clear statement of that intent, and the CSA does not contain that clear statement.

D. A clear statement is required here to support the U.S. Attorney General's threat because it would push the boundaries of Congress's authority under the Commerce Clause.

Just as intrusion on the States' historic powers calls for a clear statement of congressional intent, so, too, does administrative action at the margins of Congress's constitutional powers. *Solid Waste Agency*, 531 U.S. at 172-73. Here, the U.S. Attorney General seeks to regulate the doctor-patient relationship at the point where the doctor, acting in good faith and within the scope of affirmative state law, decides which among those medicines that concededly have approved uses he or she will prescribe to a patient to address the patient's specific medical needs. Such an action would be unprecedented and this Court previously has determined that Congress could not do as much. Resolution of that issue, moreover, must account for the negligible impact the DWDA would have on interstate commerce.

The Interstate Commerce Clause authorizes Congress to regulate in three general categories: Congress can regulate the channels of interstate commerce; it can regulate and protect the instrumentalities of interstate commerce, and persons or things in interstate commerce; and it can regulate activities that substantially affect interstate commerce. *Raich*, 125 S. Ct. at 2205 (citing *Perez v. United States*, 402 U.S. 146, 150 (1971), and *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 37 (1937)). Only the third category could be at issue here. [18]

It then becomes necessary to isolate "the precise object or activity," *Solid Waste Agency*, 531 U.S. at 173, that the U.S. Attorney General seeks to regulate. The U.S. Attorney General's directive says nothing about either the commercial aspects of the doctor-patient transaction or the amount of drugs prescribed. That may be because those amounts are unremarkable. The drugs prescribed under the DWDA, primarily secobarbital and pentobarbital, Seventh Annual Report, at 14, concededly have accepted medical uses. Standard therapeutic doses of both range from 100 mg. as a sleeping aid to somewhat more or less than that daily for sedation.[19] A lethal prescription under the DWDA would involve nine or ten grams.[20] Consequently, many

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[18] Although it is likely that the drugs in question have traveled in interstate commerce, that alone is insufficient to support an exercise of the commerce power. *Jones*; *Lopez*.

[19] U.S. National Library of Medicine and National Institutes of Health, *Medline Plus*, http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202081.html (June 27, 2005)

[20] Oregon Department of Human Services, *Fifth Annual Report on Oregon's Death With Dignity Act*, 12-13 (2003); http://egov.oregon.gov/DHS/ph/pas/docs/year5.pdf.

prescriptions for conventional purposes would not differ significantly from a prescription provided to a terminally ill patient to end his or her life. Under the U.S. Attorney General's directive, therefore, the same prescription for the same drugs would be routine, on the one hand, or cause for prosecution, deregistration, or both, on the other, depending on the patient's and the physician's knowledge about the patient's intent. And while intent matters in the law, *Vacco*, 521 U.S. 800-05, whether Congress can regulate that intent under the Commerce Clause is quite a different question. [21] Consequently, the question becomes whether a physician's or patient's intentions about the ultimate use of the drugs substantially affect interstate commerce when the physician prescribes controlled substances for the purposes permitted the DWDA rather than more common therapeutic uses.

In *Raich*, the Court found *Wickard v. Filburn*, 317 U.S. 111 (1942), to be of "particular relevance." *Raich*, 125 S. Ct. at 2206. That case, the Court concluded, establishes that Congress can regulate noncommercial, intrastate activity if failure to do so would "undercut the regulation of the interstate market in that commodity." *Id.* Comparing the marijuana at issue in *Raich* with the wheat in *Wickard*, the Court concluded that although the federal interests at stake in the two cases differed, the potential for diversion of homegrown marijuana into the illegal market had the same

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[21] Petitioners note that the directive exempts physicians who treat pain associated with illness, "even though such treatment may have the unintended consequence of hastening the patient's death." Pet. Br. 20 n. 7. Even if hastening the patient's death is "unintended," it is a readily predictable consequence of the treatment to which they refer, which makes identifying precisely what the commerce power would be regulating even more difficult.

potential to frustrate the federal interest as the potential for diversion of wheat into the regulated market because each had a "substantial effect on supply and demand in the national market for that commodity." *Raich*, 125 S. Ct. at 2207 (footnote omitted). That conclusion was bolstered by the recognition that "in 2000 American users spent $10.5 *billion* on the purchase of marijuana." *Id.* at 2208 n. 31 (emphasis in original).

The actual or even hypothetical effects of the DWDA cannot rationally be considered comparable. Between 1998, when the DWDA was implemented, and 2004, the latest complete reporting period, 208 persons in Oregon died after ingesting a lethal dose of medication prescribed pursuant to that statute. Seventh Annual Report, 20. Even if all those patients had diverted their nine or ten grams of those drugs into whatever illegal market may exist for them, the amounts would be insignificant by any measure. Thus, it could not reasonably be asserted that implementing the DWDA could rip a "gaping hole" in the CSA, *Raich*, 125 S. Ct. at 2209, or that preventing its implementation is in any sense "essential to a comprehensive regulation of interstate commerce." *Id.* at 2217 (Scalia, J., concurring in the judgment).

The Court has explained on numerous occasions that it looks for a clear statement of Congress's intent to invoke the outer limits of its constitutional powers before the Court will decide whether Congress has reached or exceeded those limits. "[W]hen a particular interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result. . . . Second, if an otherwise acceptable construction of a statute would raise serious constitutional problems, and where an alternative interpretation of the statute is fairly possible, . . . we are obligated to construe the statute to avoid such problems." *INS v. St. Cyr*, 533 U.S. 289, 299-300 (2001) (citations and

internal quotation marks omitted); *accord Jones*, 529 U.S. at 857 ("where a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter") (citation and quotation marks omitted). The rule is not observed merely to "avoid or postpone difficult decisions. The predominant consideration is that we should be sure Congress has intentionally put its power in issue by the legislation in question before we undertake a pronouncement which may have far-reaching consequences upon the powers of the Congress or the powers reserved to the several states." *United States v. Five Gambling Devices*, 346 U.S. 441, 448-49 (1953). And the Court assumes that "Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority." *Solid Waste Agency*, 531 U.S. at 172-73.

No one who follows this Court's Commerce Clause jurisprudence can fail to appreciate the significance to our federal system of the deep and abiding questions involved in *Garcia*, *Lopez*, *Morrison,* and *Raich*. That is not to suggest that all Commerce Clause cases present issues of such difficulty that the Court must always find a clear statement. But even where Congress has undoubted authority to regulate a subject matter area, profound questions can arise at the margins of that area. *Solid Waste Agency*, 531 U.S. at 172-74 (although Congress has Commerce Clause power to regulate navigable waters and some non-navigable waters, extending that power to isolated ponds would push the limit of congressional authority, thereby demanding "a clear indication Congress intended that result"). Although Oregon acknowledges, as it must, that Congress has the authority to regulate controlled substances generally, it rejects the contention that Congress could regulate the particular uses

that individual physicians, acting in good faith and pursuant to affirmative state law, can make of substances having accepted medical uses. *Linder v. United States*, 268 U.S. 5, 18 (1925) ("Obviously, direct control of medical practice in the States is beyond the power of the Federal government").[22] To grant the power claimed by the U.S. Attorney General here, the Court would, at a minimum, have to overrule *Linder* and, at worst, have to reopen the divisive question whether, even if state sovereignty is no shield against the full exercise of the Commerce Clause power, *Garcia*, all the limits on the reach of the federal sword have been identified. *E.g.*, *Jones*; *Morrison*; *Lopez*; *Printz v. United States*, 521 U.S. 898 (1997); *New York v. United States*, 505 U.S. 144 (1992). Avoiding just such difficult and potentially far-reaching questions until *Congress* unmistakably manifests its intention to raise them is a central reason for the clear statement requirement. *E.g.*, *Jones*, 529 U.S. at 858.

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[22] Petitioners argue that because *Linder* cited, among other cases, *Hammer v. Dagenhart*, 247 U.S. 251 (1918), it is a "*Lochner*-era" relic that has no continuing viability. To be sure, *Linder* relied on *Hammer*, but that case was merely one in a string citation that also included *McCulloch v. Maryland*, 4 Wheat. 316, 423 (1819). *Linder*, 268 U.S. at 17. Thus, even if part of *Linder*'s support is gone, the more important part certainly remains. And while this Court expressly overruled *Hammer*, it has not overruled *Linder*. To the contrary, years after the Court overruled *Hammer* in *United States v. Darby*, 312 U.S. 100, 116-17 (1941), the Court continued to cite *Linder* without suggesting that it lacked precedential value. *Robinson v. California*, 370 U.S. 660, 667 n. 8 (1962); *United States v. Kahriger*, 345 U.S. 22, 30 nn. 7 and 11 (1953), *overruled on other grounds Marchetti v. United States*, 390 U.S. 39, 54 (1968).

III. The Court should reject this unprecedented attempt by an agency official to resolve a disputed issue of social and medical policy that is reserved to the States and should reemphasize the vital role State sovereignty plays in our federal system and the need for Congress to speak clearly when it intends to interfere with that role.

Oregon understandably seeks to protect its sovereignty by ensuring that federal agents observe the limits of the power Congress intended to give them and that Congress observes the limits of its defined powers. Petitioners, perhaps equally understandably, appear determined to minimize the effect the Court should give to either of those limitations. In Oregon's view, this case is about statutory construction and about the principles that should guide that process when concerns of federalism and State sovereignty weigh heavily in the balance and the limits of Congress's power under the Commerce Clause are close by. Those concerns require that *Congress* have spoken with a clear voice and have made a clear statement of *Congress's* intent to infringe on the States' traditional powers. Yet petitioners can point to no clear statement in the CSA and must rely instead on ambiguous statutory language and administrative regulations and a directive purporting to interpret it.

In *Medtronic*, this Court determined that a federal statute did not bar the state-court, common-law tort actions at issue there despite the existence of "a statutory provision that expressly pre-empts state law." 518 U.S. at 484. The Court's interpretation of the statutory language was "informed by two presumptions about the nature of pre-emption." *Id.* at 485 (citation omitted). First, "because the States are independent sovereigns in our federal system, [the Court has] long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Id.* Particularly in areas where the

States' exercise "their police powers to guard the health and safety of their citizens," *id.* at 475, the Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 485 (internal quotation marks and citations omitted). Second, "[t]he purpose of Congress is the ultimate touchstone in every pre-emption case" and congressional intent "primarily is discerned from the language of the" statute. *Id.* at 485-86 (internal quotation marks and citations omitted).

In contrast to *Medtronic*, where this Court found that federal law did not displace state common-law remedies despite the existence of an express preemption provision, petitioners seek to override the DWDA not only in the absence of such a provision, but in the face of an express anti-preemption provision in the CSA. They make that attempt in an area at the heart of the States' historic police powers and at or near the outer limits of Congress's power under the Commerce Clause. The vague and elastic statutory language on which petitioners are forced to rely simply cannot bear the weight they seek to place on it. Based on statutory language that does not at all reflect "the clear and manifest purpose of Congress" to intrude on the States' traditional power to regulate medicine, petitioners seek to corral that power and place it in the hands of the U.S. Attorney General. That attempt is sweeping in its implications. If it were to succeed, the States' historic powers would be compromised and their sovereignty undermined not only when a State takes a bold step like the one Oregon has taken with respect to end-of-life issues, but in more routine matters as well. That result should not be tolerated without a clear statement of congressional intent. Because the CSA contains no clear statement of congressional intent to usurp the States' authority to regulate

the practice of medicine, it follows that this Court should affirm.

CONCLUSION

This Court should affirm the judgment of the court of appeals.

Respectfully submitted,

HARDY MYERS
Attorney General of Oregon
PETER SHEPHERD
Deputy Attorney General
MARY H. WILLIAMS
Solicitor General
ROBERT M. ATKINSON
Assistant Attorney General
Counsel for Respondent
State of Oregon

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